NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction for the Administration of Spikevax® Bivalent Original/Omicron (Moderna COVID 19) Vaccine by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Version 1

Effective from 22nd August 2022

NoS/PGD/COVID19_Spikevax_Bivalent/MGPG1296

Note: Other COVID19 vaccines are not covered by this PGD – separate PGDs will be available

This Patient Group Direction (PGD) has been adopted from the PGD template produced by Public Health Scotland issued on 22nd August 2022.

Version history

Version	Date	Summary of changes
1.0	22 August 2022	Version 1.0 new PGD

Contents

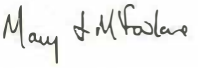
Authorisation

PGD Spikevax® Bivalent Original/Omicron (Moderna COVID-19) Vaccine

This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland to assist NHS Boards. NHS Boards should amend/adapt this PGD template and must ensure that the PGD is considered and approved in line with local clinical governance arrangements for PGDs

The qualified health professionals who may administer Spikevax® bivalent Original/Omicron (Moderna COVID-19) vaccine under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct, and to ensure familiarity with the manufacturer's product information/summary of product characteristics (SPC) for all vaccine administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same registered healthcare practitioner who have assessed the patient under the PGD.

This PGD has been produced for NOS by					
Doctor	Dr Susan Laidlaw	Signature		Date Signed	31/08/2022
Pharmacist	Mary McFarlane	Signature		Date Signed	31/08/2022
Nurse	Pauline Merchant	Signature		Date Signed	30/08/2022

Approved for use within NOS Boards by;

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		30/08/2022

Authorised and executively signed for use within NOS Boards by;

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Professor Caroline Hiscox		31/08/2022

Version 1.0 effective from 22nd August 2022 review date 31st March 2023.

Clinical situation

Category	Description
Indication	Spikevax® bivalent Original/Omicron (Moderna COVID-19) vaccine is indicated for active immunisation as a booster against COVID-19 disease caused by SARS-CoV-2 virus in accordance with Scottish Government COVID-19 immunisation programme and JCVI advice/recommendations as set out in Green Book **Chapter 14a** and subsequent correspondence/publications from Scottish Government.
Inclusion criteria	Spikevax® bivalent Original/Omicron (Moderna COVID-19) vaccine should be offered in accordance with the recommendations in Green Book **Chapter 14a**. National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time. Valid consent has been given to receive the vaccine.
Exclusion criteria	Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of COVID-19 vaccine. • have had a confirmed anaphylactic reaction to any component of the vaccine or residual products from manufacture, these include polyethylene glycol. Practitioners must check the marketing authorisation holder's summary of product characteristics (SmPC) for details of vaccine components. • have a history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed. • have a history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (e.g. depot steroid injection, laxative) unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed. • have a history of idiopathic (unexplained) anaphylaxis unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed. • are under 18 years of age

Category	Description
	• have evidence of current deterioration of COVID-19 symptoms, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine. • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • are bone marrow and peripheral blood stem cell donors who have commenced GCSF, the vaccination (first or second dose) must be delayed at least until 72 hours after stem cell collection (both peripheral blood stem cell and bone marrow donation). This is a precautionary advice to avoid vaccination when receiving Granulocyte-colony stimulating factor (GCSF) and allow for post donation recovery period. • have developed myocarditis or pericarditis following a previous dose of COVID-19 vaccination
Cautions/ need for further advice/ circumstances when further advice should be sought from a doctor	The Green Book advises that there are very few individuals who cannot receive COVID-19 vaccines. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team. **Individuals with a history of allergy** Those with a personal history of allergy should be managed in line with table 5 Green Book **Chapter 14a**. Where individuals have experienced a possible allergic reaction to a dose of COVID-19 vaccine, follow the guidance in the flowchart in Green Book **Chapter 14a** in relation to administration of subsequent doses. Green Book **Chapter 14a** states individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting. Observation for 15 minutes is recommended. No specific management is required for individuals with a family history of allergies. **Individuals with thrombocytopenia** Guidance produced by the UK ITP Forum Working Party advises discussing the potential for a fall in platelet count in patients with a history of immune thrombocytopenia (ITP) receiving any COVID-19

Category	Description
	vaccine and recommends a platelet count check 2-5 days after vaccination. **Guillain-Barré syndrome (GBS)** Very rare reports have been received of GBS following COVID-19 vaccination. Healthcare professionals should be alert to the signs and symptoms of GBS to ensure correct diagnosis and to rule out other causes, in order to initiate adequate supportive care and treatment. Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. In those who are diagnosed with GBS after the first dose of vaccine, the balance of risk benefit is in favour of completing a full COVID-19 vaccination schedule. On a precautionary basis, however, where GBS occurs within six weeks of an Astra Zeneca vaccine, for any future doses Pfizer or Moderna COVID-19 vaccines are preferred. Where GBS occurs following either of the mRNA vaccines, further vaccination can proceed as normal, once recovered. **Individuals with a bleeding history** Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration). **Co-administration with other vaccines** The COVID-19 vaccines in use in the UK are considered inactivated, where individuals in an eligible cohort present having recently received another inactivated or live vaccine, COVID-19 vaccination should still be given. The same applies for most other live and inactivated vaccines where COVID-19 vaccination has been received first or where a patient presents requiring two or more vaccines. It is generally better for vaccination to proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. This includes but is not limited to vaccines commonly administered around the same time or in the same settings (including influenza and pneumococcal polysaccharide vaccine in those aged over 65 years, pertussis-containing vaccines and influenza vaccines in pregnancy, and LAIV, HPV, MenACWY and Td-IPV vaccines in the schools programmes). An exception to this is shingles vaccination, where a seven-day interval should ideally be observed given the potential for an inflammatory response to COVID-19 vaccine to interfere with the response to the live virus in the older population and because of the potential difficulty of attributing systemic side effects to the newer adjuvanted shingles

Category	Description
	vaccine. Where individuals attend requiring both vaccines, however, and require rapid protection or are considered likely to be lost to follow up, co-administration may still be considered. When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. Where co-administration does occur, patients should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects. **Syncope** Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. **Pregnancy and breastfeeding** JCVI advise there is no known risk associated with giving these types of vaccines during pregnancy. These vaccines cannot replicate, so they cannot cause infection in either the woman or the unborn child. Vaccination in pregnancy should be offered in accordance with recommendations in Green Book Chapter 14a, following a discussion of the risks and benefits of vaccination with the woman. In December 2021, following the recognition of pregnancy as a risk factor for severe COVID-19 infection and poor pregnancy outcomes during the Delta wave, pregnancy was added to the clinical risk groups recommended COVID-19 vaccination. Because of the wider experience with mRNA vaccines, these are currently the preferred vaccines to offer to pregnant women. For those under 18 years Comirnaty® (COVID-19 mRNA vaccine,

Category	Description
	Pfizer/BioNTech) is preferred. When mRNA vaccines are not considered clinically suitable, Nuvaxovid (Novavax COVID-19 vaccine recombinant, adjuvanted) vaccine may be used for primary vaccination of pregnant women, including to complete a course or as a booster, although experience in pregnancy is relatively limited. If a woman finds out she is pregnant after she has started a course of vaccine, she should complete vaccination at the recommended interval. There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with any suitable COVID-19 vaccine. Emerging safety data is reassuring: mRNA was not detected in the breast milk of recently vaccinated and protective antibodies have been detected in breast milk. The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19. **Clinical trial participants** Individuals who have participated in a clinical trial of either primary or booster COVID-19 vaccines should be provided with written advice on whether and when they should be safely vaccinated in the routine programme. Advice should also be provided from the trial investigators on whether any individual could receive additional doses for the purposes of vaccine certification. Trial participants who are eligible for boosters should be offered vaccination in line with the general population, at least three months after the dose considered as the final primary dose or the final revaccination (if the latter is required for certification purposes). **Individuals with a past history of COVID-19 infection** There is no convincing evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. As clinical deterioration can occur up to two weeks after infection, vaccination of adults and high risk children* should ideally be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen to avoid confusing the differential diagnosis.

Category	Description
	The four-week interval may be reduced to ensure operational flexibility when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. Currently, the JCVI consider that, in care home residents and the housebound, there may be an advantage in offering vaccination to some individuals with recent confirmed COVID-19, without a four-week deferral, where individuals are clinically stable and when infection control procedures can be maintained. These populations are likely to be highly vulnerable and will facilitate vaccination without the need for multiple visits. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical or epidemiological features to suggest the episode was COVID-19 infection. *high risk will include children and young people under 18 years as defined in tables 3 and 4 of Green Book **Chapter 14a** and includes clinical risk groups and individuals who expect to share living accommodation on most days (and therefore for whom continuing close contact is unavoidable) with individuals who are immunosuppressed.
Action if excluded	Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in accordance with local procedures. Inform or refer to the clinician in charge. In case of deferral due to COVID-19 symptoms or recent positive COVID test advise when the individual can be vaccinated and how future vaccination may be accessed. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.
Action if patient declines	Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine. Document advice given and decision reached.

Category	Description
	Inform or refer to the clinician in charge.

Description of treatment

Category	Description
Name of medicine	Spikevax® bivalent Original / Omicron (Moderna COVID-19) Vaccine dispersion for injection Spikevax® 0 (Zero)/O (Omicron) (Moderna COVID-19) Vaccine dispersion for injection
Form/strength	Spikevax® bivalent Original / Omicron (Moderna COVID-19) Vaccine dispersion for injection 0.10mg/ml, multi dose vial Spikevax® 0 (Zero)/O (Omicron) (Moderna COVID-19) Vaccine dispersion for injection 0.10mg/ml, multi dose vial
Route of administration	Each vial contains at least the number of doses stated. It is normal for liquid to remain in the vial after withdrawing the final dose. Care should be taken to ensure a full 0.5 mL dose is administered. Where a full 0.5 mL dose cannot be extracted, the remaining volume should be discarded. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. Spikevax® bivalent Original / Omicron (Moderna COVID-19) Vaccine must be administered by intramuscular (IM) injection preferably into the deltoid area of the upper arm. Where administration into the deltoid is not possible the anterolateral thigh can be considered. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/ treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR is below the

Category	Description
	upper level of the therapeutic range, can receive intramuscular vaccination. A fine needle (23 or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site without rubbing for at least 2 minutes. The individual/parent/carer should be informed about the risk of haematoma from the injection.
Dosage	0.5ml
Frequency	Spikevax® bivalent Original / Omicron (Moderna COVID-19) vaccine as a booster in those who have received primary immunisation (and previous boosters) should be offered a single dose at least 3 months (12 weeks) after previous COVID-19 dose. Someone in the eligible group who has received a full course of primary vaccination (two or three doses) but has not received a booster before September 2022, may be given a booster provided there is at least three months from the previous dose. Additional doses are not then required.
Duration of treatment	See above.
Maximum or minimum treatment period	See above.
Quantity to supply/administer	See above.
▼ black triangle medicines	Yes, Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine is subject to additional monitoring and id designated as ▼ Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on **http://www.mhra.gov.uk/yellowcard**
Legal category	Prescription only medicine (POM).
Is the use out with the SPC?	Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine has been granted a Conditional Marketing Authorisation (CMA) by the MHRA

Category	Description
	The vaccine marketing authorisation holder's SmPC states that close observation for at least 15 minutes is recommended following vaccination. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant, the UK Chief Medical Officers have recommended temporary suspension of this requirement. This temporary suspension in individuals without a history of allergy has also been agreed by the Commission on Human Medicines. This also applies to Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine The Scottish Government has made further recommendations that all doses of COVID-19 vaccines be followed by a 5 minute observation period. Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to national Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.
Storage requirements	Spikevax® bivalent Original/Omicron (Moderna COVID 19) vaccine must be stored frozen at minus 50ºC to minus 15ºC in accordance with manufacturer's advice. Once thawed, the vaccine should not be re-frozen and may be stored refrigerated at +2°C to +8°C protected from light for up to 30 days if not used (needle-punctured). During storage it is recommended that the vials are stored in the original packaging/cartons, away from direct sunlight to protect from light and kept upright. NHS Board guidance on Storage and Handling of vaccines should be observed. In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued use or appropriate disposal. After first use – use as soon as practically possible and within six hours. The vaccine may be stored between +2 and +25°C during the in-use period in accordance with manufacturer's advice. . The vaccine vial has space to write the date and time that the vial should be discarded following first puncture; write this on the vial label.

Category	Description
	The manufacturer may advise of updated storage requirements and product stability as new data becomes available, vaccine may be stored in accordance with updated recommendations from the manufacturer.
Additional information	Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered. There is no convincing evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the patient is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.

Adverse reactions

Category	Description
Warnings including possible adverse reactions and management of these	A high proportion (more than 75%) of vaccine recipients had localised pain at the injection site after both dose 1 and dose 2 of Spikevax® (COVID-19 Vaccine Moderna dispersion for injection). Redness and swelling were also seen after the second dose and local pain tended to last longer (around 3 days). Mild systemic effects were also common, including headache, fatigue, joint and muscle aches and chills. Systemic events were more severe after dose 2 and fever was only seen after dose 2, and both local and systemic reactions were less common in older participants. Adverse events were less common in those with pre-existing SARS-CoV-2 antibody. Axillary lymphadenopathy on the same side as the injection site was detected in more than one in ten recipients. Bell's palsy was reported by three participants in the vaccine group and one participant in the placebo group. As for the Pfizer vaccine, this will be monitored closely post-implementation. There were no cases of severe COVID-19 disease in the vaccine group, and thus no signal for enhanced disease. A number of cases of myocarditis and pericarditis have been reported after Pfizer BioNTech vaccine from Israel and the USA. The reported rate appears to be highest in those under 25 years of age and in males,

Category	Description
	and after the second dose. Onset is within a few days of vaccination and most cases are mild and have recovered without any sequalae. The MHRA has advised the benefits of vaccination still outweigh any risk in most individuals. Individuals who have had myocarditis or pericarditis should be investigated, and a second or booster dose can be given once they are fully recovered in line with advice in the Green Book **Chapter 14a**, under a PSD. Reactogenicity was similar between the original and bivalent vaccine. In the event of a severe adverse reaction individual should be advised to seek medical advice. For full details/information on possible adverse reaction, refer to manufacturer's product literature or summary of product characteristics.
Reporting procedure for adverse reactions	Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on **http://www.mhra.gov.uk/yellowcard** Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed. Anaphylaxis is a very rare, recognised side effect of most vaccines and suspected cases should be reported via the MHRA Yellow Card Scheme. Chapter 8 of the Green Book gives detailed guidance on distinguishing between faints, panic attacks and the signs and symptoms of anaphylaxis. If a case of suspected anaphylaxis meets the clinical features described in Chapter 8, this should be reported via the Yellow Card Scheme as a case of 'anaphylaxis' (or if appropriate 'anaphylactoid reaction'). Cases of less severe allergic reactions (i.e. not including the clinical features of anaphylaxis) should not be reported as anaphylaxis but as 'allergic reaction'. Programmatic Adverse Events should be recorded in line with local procedures and where appropriate escalated in accordance with the national framework.
Advice to patient or carer including written information	Written information to be given to individual • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. • Provide copy of Public Health Scotland post-vaccination leaflet

Category	Description
	• Provide copy of Pregnant, planning a pregnancy or breastfeeding, a guide to COVID-19 vaccine to women of child bearing years Individual advice / follow up treatment • Inform the individual/carer of possible side effects and their management. • Vaccinated individuals should be advised that it is common to develop a fever after vaccination and that this normally happens within 48 hours after the vaccination and usually goes away within 48 hours. This is a common, expected reaction, and self-isolation and testing for COVID-19 are not required. • Vaccinated individuals should be advised that if the fever started 48 hours after the vaccination or lasts longer than 48 hours, they should seek medical advice as they may have COVID-19 or another infection. • Vaccinated individuals should be advised that feeling generally unwell, shivery, achy and tired were also symptoms commonly reported by vaccine recipients in the clinical trials. Generally, these symptoms were found to resolve within one to two days without treatment but paracetamol can be taken if necessary to relieve any of these symptoms. • Inform the individual/carer that anyone who has any of the following symptoms after vaccination should seek medical advice urgently: ○ chest pain ○ shortness of breath ○ feelings of having a fast-beating, fluttering, or pounding heart • As has always been recommended, any fever after vaccination should be monitored and if individuals are concerned about their health at any time, they should seek advice from their GP or NHS24 • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: **http://www.mhra.gov.uk/yellowcard** • Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine and they should continue to take appropriate measures to protect themselves against this infection.

Category	Description
	• When administration is postponed advise the individual how future vaccination may be accessed
Observation following vaccination	Following COVID-19 vaccine administration, individuals should be observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre. According to the Summaries of Product Characteristics, it is recommended that all recipients of the Pfizer BioNTech, Moderna and Novavax vaccines are kept for observation and monitored for a minimum of 15 minutes. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant, the UK Chief Medical Officers have recommended suspension of this requirement. This temporary suspension in individuals without a history of allergy has also been agreed by the Commission on Human Medicines. The Scottish Government has made further recommendations that all doses of mRNA COVID-19 vaccines be followed by a 5 minute observation period. A longer observation period when indicated after clinical assessment in individuals with a history of allergy as set out in Table 5 and flowchart in Green Book **Chapter 14a** Vaccinated individuals should be informed about how to access immediate healthcare advice in the event of displaying any symptoms. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.
Follow up	Not applicable
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer vaccines: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) • chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • dental hygienists and dental therapists registered with the General Dental Council • optometrists registered with the General Optical Council
Specialist competencies or qualifications	Persons must only work under this PGD where they are competent to do so. All practitioners operating this PGD must: • demonstrate appropriate knowledge and skills to work under the PGD for the administration of COVID-19 vaccine. • have met the requirements of the NES Proficiency document - COVID-19 vaccine administration for registered staff or the NES Proficiency document –COVID-19 vaccine administration. This NES Proficiency document can be found at TURAS Learn at: **https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines** All persons operating this PGD: • must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it • must be familiar with the vaccine product and alert to changes in the manufacturers product information/summary of product information, • must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent

Category	Description
	• must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine • must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of COVID-19 vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under the PGD Employer • The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD • As a minimum, competence requirements stipulated in the PGD must be adhered to.
Continuing education and training	All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of COVID-19 vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

Audit trail

Name	Description
Record/ audit trail	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • batch number • where possible expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • administered under PGD Records should be kept line with local procedures. Local policy should be followed to encourage information sharing with the individual's General Practice. All records should be clear, legible and contemporaneous.

Additional references

Name	Description
Additional references	Immunisation against Infectious Disease [Green Book] **https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book** Immunisation against Infectious Disease [Green Book] COVID-19 **https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a** Manufacturer's product information/ Summary of Product Characteristics **https://www.gov.uk/government/publications/regulatory-approval-of-spikevax-bivalent-originalomicron-booster-vaccine** Educational resources for registered professionals produced by National Education for Scotland **https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines** All relevant JCVI statements All relevant Scottish Government advice including the relevant CMO letter(s)

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Health Board, Area Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

Patient Group direction for the administration of Spikevax® Bivalent Original/Omicron (Moderna COVID 19) Vaccine by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles (Version 1.0 – valid from 22nd August 2022)

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction. **PGDs do not remove inherent professional obligations or accountability.**

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2

Healthcare Professional Authorisation to Administer Vaccine Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the vaccine under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
Patient Group direction for the administration of Spikevax® Bivalent Original/Omicron (Moderna COVID 19) Vaccine by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles (Version 1.0 – valid from 22nd August 2022)
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**